



***Anthrax
Vaccine
Immunization
Program***

Individual Briefing

**Post – EUA
Continuation Policy**



History of AVIP

- Secretary of Defense ordered the AVIP in Dec 97
- Vaccinations began in Southwest Asia in Mar 98
- Vaccinations began in Korea in Aug 98
- Slowdowns in 2000-01. After supply restored, program resumed 2002
- Injunction issued October 2004
- FDA issues Emergency Use Authorization (EUA) January 2005
- FDA formally concludes Anthrax Vaccine is effective regardless of route of exposure, 19 DEC 2005
- DoD leadership is reviewing the Final Order
- For now, Anthrax vaccinations continue as during EUA: same people, voluntary basis

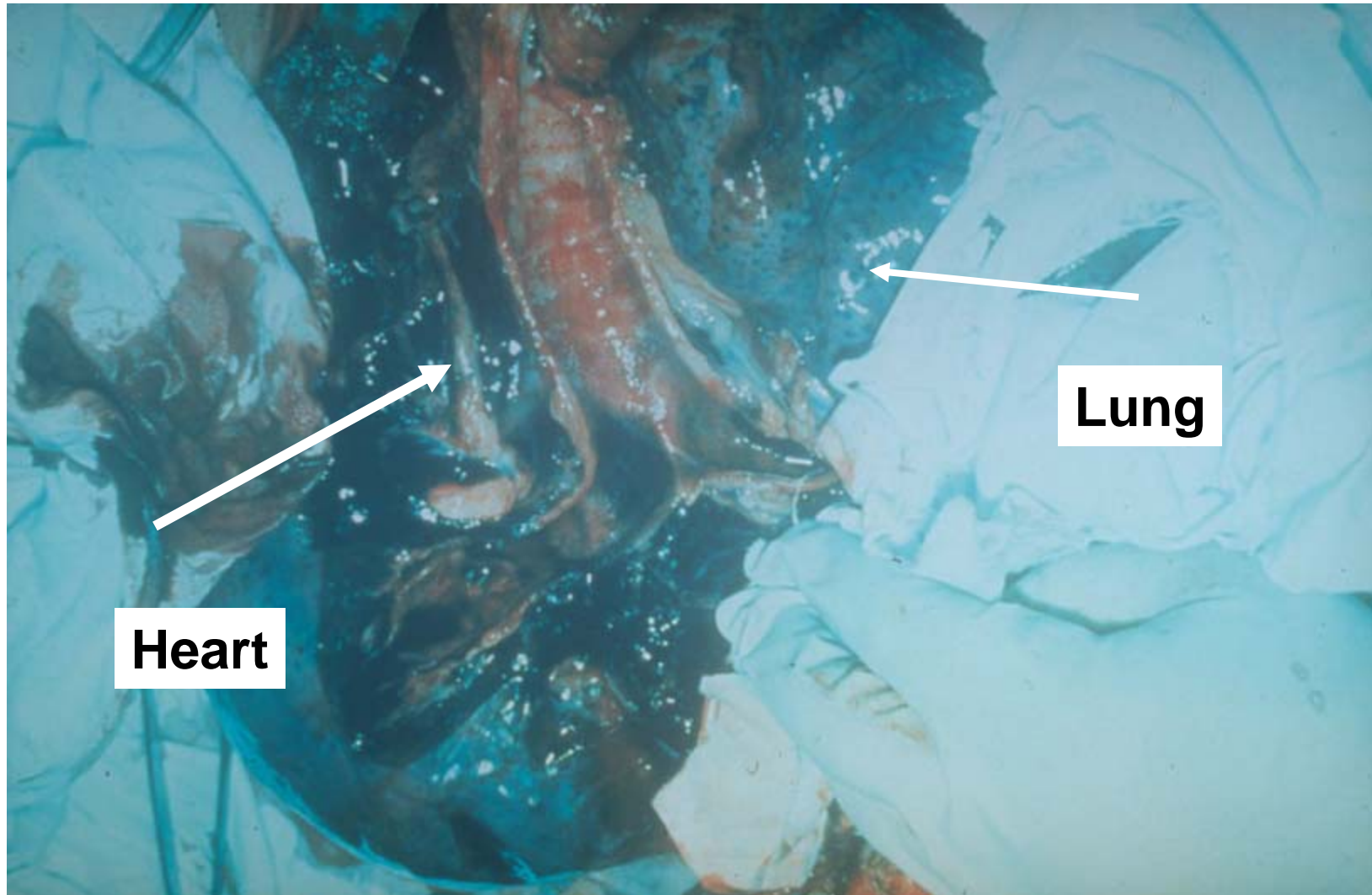
Anthrax Spores

- Highly lethal – Inhaling spores can kill 99% of unprotected, unvaccinated, untreated people
- Extremely stable - withstands harsh conditions, remains inactive for up to 50 years
- Resists heat, ultraviolet light, gamma radiation, bleach
- Easily weaponized and deployed – bombs, missiles, mailed packages, aerosols
- Colorless, odorless, difficult to detect
- At least 7 potential adversaries suspected of researching, developing, or weaponizing anthrax
- You can be infected and not know it, until it's too late.

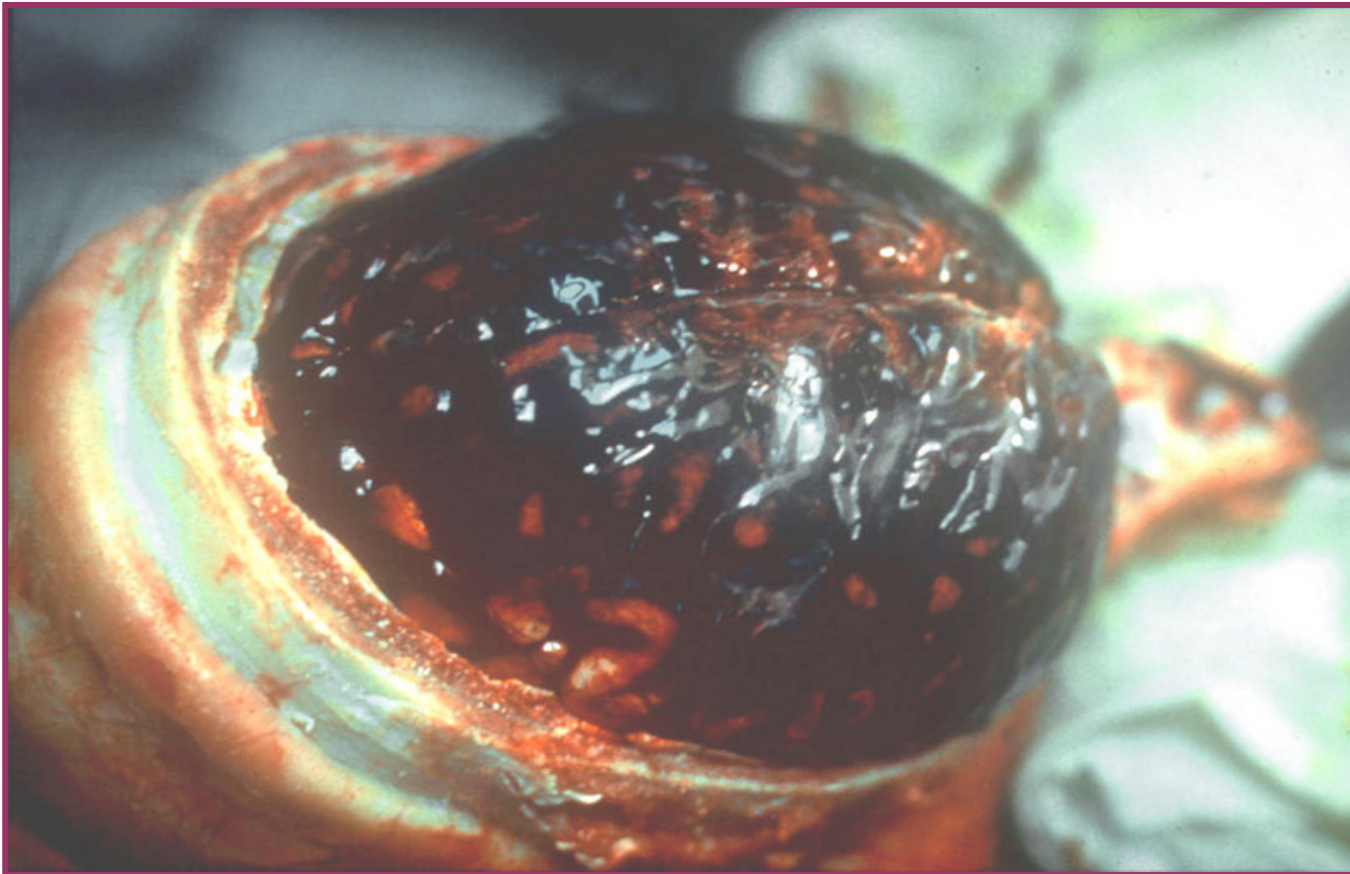
Largest Human Outbreak of Anthrax

- Sverdlovsk, USSR, 1979
- Anthrax spores accidentally released from a military microbiology facility
- 77 people infected
- 66 of these people died (86% death rate)
- Most victims worked or lived within 4-kilometer zone south of the city
 - Investigators concluded anthrax spores spread where the wind blew

Lethal Case of Inhalation Anthrax



Lethal Case of Inhalation Anthrax



Letter with Anthrax Spores, Fall 2001

09-11-01
YOU CAN NOT STOP US.
WE HAVE THIS ANTHRAX.
YOU DIE NOW.
ARE YOU AFRAID?
DEATH TO AMERICA.
DEATH TO ISRAEL.
ALLAH IS GREAT.

4TH GRADE
GREENDALE SCHOOL
FRANKLIN PARK NJ 08852

SENATOR DASCHLE
509 HART SENATE OFFICE
BUILDING
WASHINGTON D.C. 20510

October 2001 Anthrax Attacks

- Several letters containing anthrax spores sent in mail
- 4 regions affected in US
 - Florida
 - New York / New Jersey
 - Washington, DC, metropolitan area
 - Connecticut
- Additional contamination of other postal facilities
- Nationwide effects
- 22 people infected:
 - 11 inhalation cases, 5 died (45% death rate)
 - 11 cutaneous (skin) cases, 7 confirmed cases (including a baby), plus 4 suspected cases
- Over 33,000 people given antibiotics

Timeline of Anthrax Postal Attacks

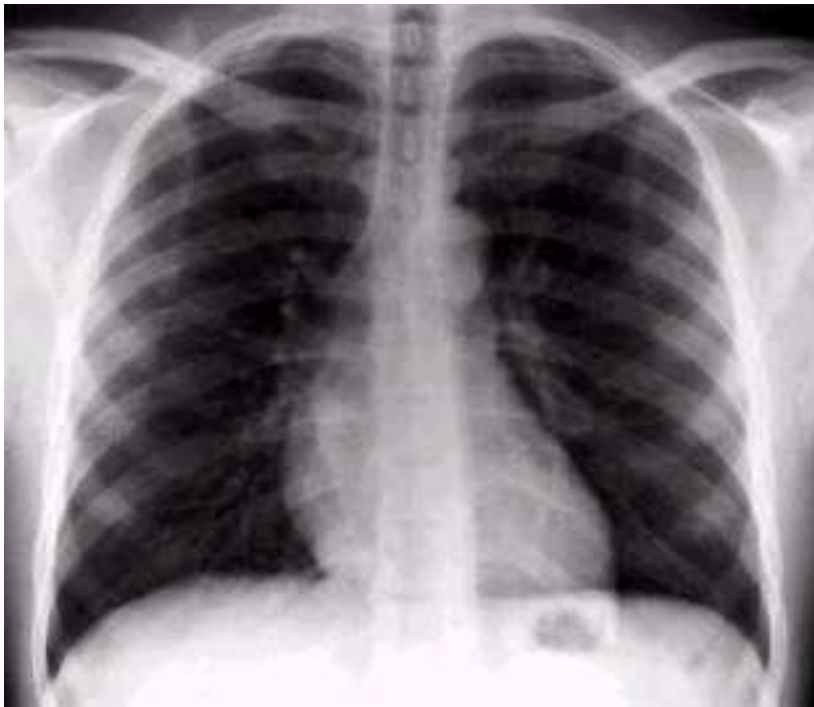
- 4 Oct 01. American Media Inc. (AMI) photo editor diagnosed with inhalation anthrax. He died the next day.
- 16 Oct 01. Without knowing they had been exposed, four Washington area postal workers developed inhalation anthrax symptoms. Two died. The Brentwood postal facility is now named the Curseen-Morris Processing & Distribution Center in their memory.
- 25 Oct 01. A hospital supply worker in New York City with no obvious exposure becomes ill. She died 5 days later from inhalation anthrax.
- 14 Nov 01. A 94-year-old woman in rural Connecticut with no obvious exposure becomes ill. Diagnosis: inhalation anthrax. She died 1 week later.

First Anthrax Case of 2001

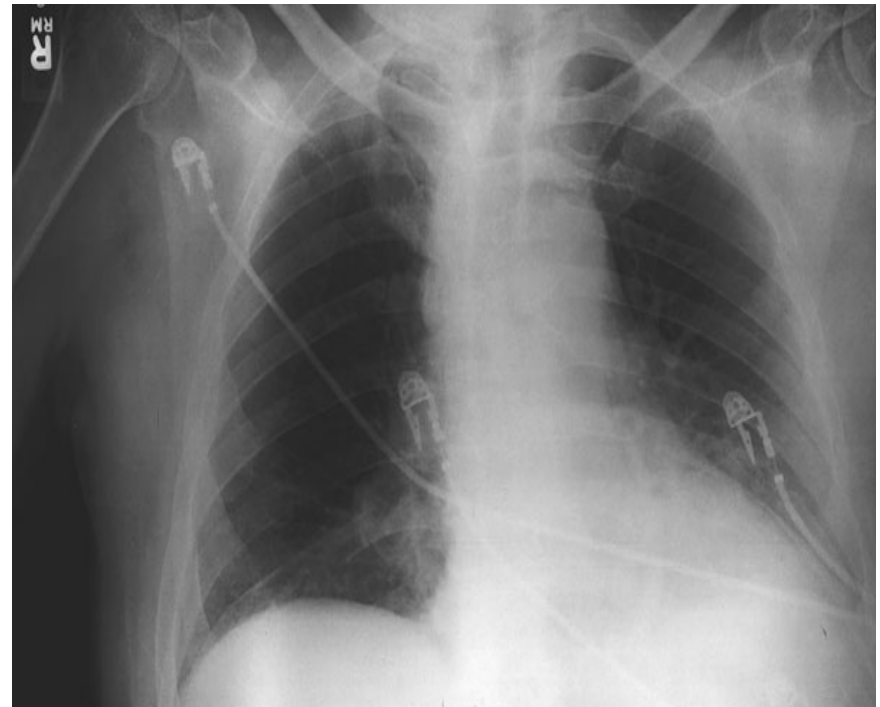
- October 2, 2001, 63-year-old photo editor wakes up nauseous, vomiting and confused
- Taken to emergency room for evaluation
 - High fever, increased heart rate, normal blood pressure and breathing
- Chest X-ray showed enlarged chest cavity
- Anthrax bacteria detected in blood
- Patient admitted to hospital, starts antibiotic therapy
 - Seizures shortly after admission
 - Chest tubes used to help breathing
 - Antibiotics continued on day 2
 - Patient unresponsive, condition worsened
- October 5, 2001, patient died

Chest X-Ray in Anthrax

Florida photo editor who died 5 October 2001



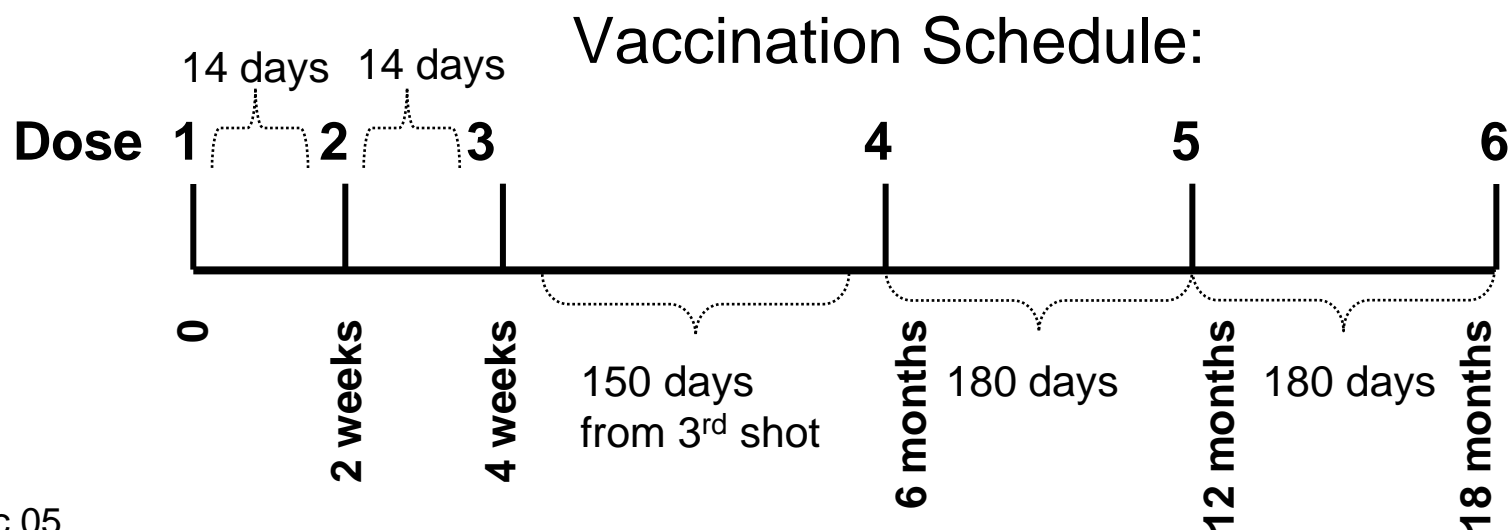
Normal Chest X-ray



**Chest X-ray of Inhalation Anthrax
Victim**

Anthrax Vaccine Facts

- Manufactured by BioPort Corporation in Lansing, Michigan
- A study in mill workers showed anthrax vaccine was 92.5% effective in preventing anthrax cases (including both cutaneous and inhalation anthrax)
- Each vaccine lot is okayed by FDA before shipment
- No other product is approved by FDA to prevent anthrax before exposure



Anthrax Vaccine Safety

- **Over 1.3 million people vaccinated with over 5.3 million doses**
- **Injection-site reactions common:**
 - 30% of men, 60% of women have injection-site reactions
 - Burning, soreness, redness, itching, swelling, or pain
- **Systemic symptoms (beyond injection site):**
 - 5% to 35% of both genders
 - Muscle or joint aches, headaches, rashes, chills, mild fever, fatigue, swelling may extend below elbow
- **Acute allergic reactions after any vaccine, 1 in 100,000 doses**
- **The risk of any vaccine causing serious harm or death is very small**
- **Consult your health care provider if adverse events occur**

Exemptions from Vaccination

- **Some people should not get anthrax vaccine.**
- **Temporary medical exemptions include:**
 - Women who are pregnant, or might be pregnant
 - Acute diseases, surgery
 - Short-term immune suppression
 - Medical evaluation or condition pending
- **Permanent exemptions can include:**
 - Severe allergic reaction or other serious reaction after a previous dose of anthrax vaccine
 - People with a possible history of latex sensitivity
 - HIV infection or other chronic immune deficiencies
 - People who had Guillain-Barré syndrome (GBS)
 - Recovery from previous anthrax infection

Adverse Event Reporting

- **Vaccine Adverse Event Reporting System (VAERS):**
 - FDA and CDC review 100% of adverse-event reports
 - All VAERS forms reviewed by independent panel of expert civilian physicians for 4 years
- **DoD requires healthcare workers submit a VAERS Form for:**
 - Loss of duty 24 hours or longer (≥ 1 duty day)
 - Hospitalization
 - Suspected vaccine vial contamination
- **Other submissions are encouraged.**
- **Anyone can submit a VAERS Form !**
- **VAERS Forms may be obtained from:**
 - Your clinic, 1-800-822-7967, or www.vaers.org

Reserve Component Adverse Events

- **Adverse events after DoD- or USCG-directed vaccinations are line-of-duty conditions**
- **Someone with an adverse event in a non-duty status possibly associated to any vaccination:**
 - Seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
 - Report the event to your unit commander or designated representative as soon as possible
 - Consider VAERS submission
- **Commander will determine Line of Duty and/or Notice of Eligibility status, if required**

Key Messages

- Your health and safety are our #1 concern.
- The threat from anthrax spores is deadly and real.
- America's best scientists say anthrax vaccine protects and is safe.
- Vaccination protects you, your unit, and your mission.
- We strongly recommend anthrax vaccination to keep you healthy.

For More Information

- Military Vaccine (MILVAX) Agency
 - Website: www.anthrax.mil www.vaccines.mil
 - Toll-Free: [877.GET.VACC](tel:877.GET.VACC)
 - E-Mail: vaccines@amedd.army.mil

- For clinical consultation or exemption assistance
 - DoD Vaccine Clinical Call Center: [866.210.6469](tel:866.210.6469)
 - Website: www.vhcinfo.org
 - E-Mail: askVHC@amedd.army.mil

- CDC National Immunization Hotline
 - Website: www.bt.cdc.gov
 - Toll-Free: [800.232.2522](tel:800.232.2522)